RESPONSE

I. Restriction Requirement

The Examiner has determined that the original claims are directed to six separate and distinct inventions under 35 U.S.C. § 121, as follows:

Group I: Claims 1-3, said to be drawn to nucleic acids and vectors encoding a human β-thymosin peptide, classified in class 435, subclass 320.1.

Group II: Claim 4, said to be drawn to a human β-thymosin peptide, classified in class 530, subclass 324.

II. Response to Restriction Requirement

In response to the Restriction Requirement, Applicants hereby confirm the election without traverse, made by Applicants' representative Peter Seferian during a telephone conference with an Examiner to prosecute the claims of Group I invention (claims 1-3), said to be drawn to nucleic acids and vectors encoding a human β-thymosin peptide, classified in class 435, subclass 320.1. Accordingly, Claim 4 has been cancelled without prejudice and without disclaimer as being drawn to non-elected inventions.

Applicants reserve the right to refile claims to the non-elected inventions in one or more future applications retaining the priority date of the present case and the earlier cited priority applications.

III. Status of the Claims

Claims 4 and 1 have been cancelled without prejudice or disclaimer. Claim 2 has been amended and claims 5 -8 have been added to better claim the present invention. As a result claims 2, 3, 5-8 are presently pending in this case.

IV. Support for the Amended Claims

Claim 2 has been revised to further clarify the claim, and to recite specific highly stringent hybridization conditions. Revised Claim 2 finds support in the application as originally filed with

particular support being found on or about page 4, lines 16-24.

Claim 5 has been added to better claim the present invention. New Claim 5 is supported by the specification as originally filed with particular support being found in original Claim 3 and the sequence listing.

Claim 6 has been added to better claim the present invention. New Claim 6 is supported by the specification as originally filed with particular support being found in original Claim 1 and the sequence listing.

Claim 7 has been added to better claim the present invention. New Claim 7 is supported by the specification as originally filed with particular support being found on or about page 13, lines 24-30.

Claim 8 has been added to better claim the present invention. New Claim 8 is supported by the specification as originally filed with particular support being found in original Claim 3, the sequence listing and as with Claim 7, particular support being found on or about page 13, lines 24-30.

As the amendments to claim 2 and new claims 5-8 are fully supported by the specification, the sequence listing and claims as originally filed, they do not constitute new matter. Entry therefore is respectfully requested.

V. Rejection of Claims Under 35 U.S.C. § 112, Second Paragraph

The Action rejects Claim 1 under 35 U.S.C. § 112, second paragraph, as allegedly being indefinite for use of the phrase "first" disclosed. While Applicants do not necessarily agree with the present rejection, as Claim 1 has been cancelled without prejudice or disclaimer this rejection has been rendered moot. Applicants therefore respectfully request the withdrawal of this rejection.

The Action next rejects Claim 2 under 35 U.S.C. § 112, second paragraph, as allegedly being indefinite for failing to particularly point out and distinctly claim the invention.

The Action rejects Claim 2 as allegedly indefinite based on the term "stringent hybridization conditions", because the specific hybridization and washing conditions are not recited in the claim. Applicants stress that "a claim need not 'describe' the invention, such description being the role of the disclosure". *Orthokinetics, Inc. v. Safety Travel Chairs, Inc.*, 1 USPQ2d 1081, 1088 (Fed. Cir. 1986). However, while Applicants submit that the term is sufficiently definite, as a number of stringent hybridization conditions are defined in the specification and would be known to those of skill in the art,

solely in order to progress the case more rapidly toward allowance the claim has been revised to recite specific highly stringent hybridization conditions. As the specification provides specific teaching regarding such highly stringent hybridization conditions, at least on or about page 4, lines 16-24. Applicants submit that revised Claim 2 even more clearly meets the requirements of 35 U.S.C. § 112, second paragraph. Applicants therefore request withdrawal of this rejection.

VI. Rejection of Claim 1 Under 35 U.S.C. § 112, First Paragraph

The Action next rejects claim 1 under 35 U.S.C. § 112, first paragraph, as allegedly containing subject matter that was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventors, at the time the application was filed, had possession of the claimed invention. Applicants in no way agree with the present rejection, however, as Claim 1 has been cancelled without prejudice or disclaimer, this rejection has been rendered moot. Applicants therefore respectfully request the withdrawal of this rejection.

VII. Rejection of Claim 1 Under 35 U.S.C. § 112, First Paragraph

The Action next rejects claim 1 under 35 U.S.C. § 112, first paragraph, as allegedly because the specification does not enable any nucleic acid comprising 24 contiguous bases of SEQ ID NO:1. While Applicants in no way agree with this rejection, as Claim 1 has been cancelled without prejudice or disclaimer, this rejection has been rendered moot. Applicants therefore respectfully request the withdrawal of this rejection.

VIII. Rejection of Claims Under 35 U.S.C. § 102(e)

The Action next rejects the claims under 35 U.S.C. § 102(e), as allegedly anticipated by Spytek, *et al.* (WO 01/90155; "Spytek"). Applicants respectfully traverse.

Without in any way acquiescing with the stated rejection, and solely to progress the case more rapidly to allowance, Applicants elect to remove Spytek as prior art. Applicants therefore provide herewith a declaration under 37 C.F.R. § 1.131 to remove Spytek as prior art.

Rule 131 provides in part that when any claim of an application is rejected under 35 U.S.C. § 102(e), the inventor(s) of the subject matter of the rejected claim may submit an

appropriate oath or declaration to overcome the publication or patent; and the cited publication or patent shall not then bar the grant of a patent to the inventor of the claims.

The declaration and the attached notebook copy meet all the requirements of MPEP 715. Applicants have elected to proceed under MPEP 715.07 and to remove particular dates from the scientific exhibits enclosed with the declaration (see section entitled "ESTABLISHMENT OF DATES", MPEP page 700-231).

The executed Rule 131 declaration of the co-inventors, D. Wade Walke and John Scoville, is enclosed herewith to evidence an invention date for the claimed invention in the United States prior to May 24, 2000, the effective filing date for the U.S. provisional application 60/206,688 in which Spytek first disclosed SEQ ID NOS: 3 and 4. The Exhibit to the declaration presents evidence of the facts set forth in the declaration, and shows that the presently claimed invention was conceived in the United States prior to May 24, 2000, and diligently reduced to practice in the United States, thus removing Spytek as prior art.

The rejection of the claims under 35 U.S.C. § 102(e) has thus been overcome. Applicants therefore respectfully request the withdrawal of this rejection.

IX. Rejection of Claim 1 Under 35 U.S.C. § 102(a)

The Action next rejects the Claim 1 under 35 U.S.C. § 102(a), as allegedly anticipated by GenBank Accession No: AW620090. While Applicants in no way agree with this rejection, as Claim 1 has been cancelled without prejudice or disclaimer, this rejection has been rendered moot. Applicants therefore respectfully request the withdrawal of this rejection.

X. Conclusion

The present document is a full and complete response to the Action. In conclusion, Applicants submit that, in light of the foregoing remarks, the present case is in condition for allowance, and such favorable action is respectfully requested. Should Examiner Prouty have any questions or comments,

or believe that certain amendments of the claims might serve to improve their clarity, a telephone call to the undersigned Applicants' representative is earnestly solicited.

Respectfully submitted,

December 22, 2003
Date

Lance K. Ishimoto Reg. No. No. 41,866
Agent for Applicants

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Customer # 24231

IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

Applicant(s):	Walke *et al.*	Group Art Unit:	1652
Application No.:	09/915,178	Examiner:	R.E. Prouty
Filed:	7/24/2001		
Title:	Novel Human Thymosin Protein and Polynucleotides Encoding the Same	Atty. Docket No.:	LEX-0205-USA

DECLARATION UNDER 37 C.F.R. §1.131 BY D. WADE WALKE

Commissioner for Patents
Alexandria, VA 22313

I, **D. WADE WALKE** and **JOHN SCOVILLE** , HEREBY DECLARE AS FOLLOWS:

1. We are co-inventors of the subject matter disclosed and claimed in the above-captioned patent application.

2. I, D. Wade Walke, am a Associate Director of Mining & Curation at Lexicon Genetics Incorporated.

3. I, John Scoville, am the Manager of the Genomic Core Facilities at Lexicon Genetics Incorporated.

4. In the above-captioned patent application, we are claiming nucleic acid molecules, expression vectors and host cells that comprise the nucleotide sequence of SEQ ID NO:1 or that encode the amino acid sequence shown in SEQ ID NO:2.

6. We have reviewed the first Official Action issued by the U.S. Patent and Trademark Office Examiner in charge of assessing the patentability of the above-captioned patent application. We understand that the Examiner has entered a 102(e) rejection based upon Spytek, *et al.* (WO

01/90155). We further understand that the Examiner believes the foregoing PCT application to be based on a U.S. provisional application, 60/206,688,and that this provisional application anticipates the claims of the present patent application.

7. We understand that SEQ ID NOS: 3 and 4 of Spytek, *et al.* (WO 01/90155) were first disclosed by Spytek, *et al.* in a U.S. provisional application 60/206,688, as such the effective filing date of Spytek, *et al.* (WO 01/90155) for the subject matter of SEQ ID NOS: 3 and 4 is May 24, 2000.

8. We are providing the present declaration and attached documentary evidence to demonstrate that we conceived the invention claimed in the above-captioned patent application in the United States prior to May 24, 2000, *i.e.*, prior to date that the U.S. provisional application 60/206,688 was filed.

9. We are also providing the present declaration and attached documentary evidence to demonstrate that the invention claimed in the above-captioned patent application was made in the United States prior to May 24, 2000, *i.e.*, prior to date that the U.S. provisional application 60/206,688 was filed.

10. Evidence of the fact that the invention claimed in the above-captioned patent application was made in the United States prior to May 24, 2000, is represented in **Exhibit A**, attached hereto. In keeping with common practice, all dates have been redacted from the Exhibit.

11. I, D. Wade Walke confirm that the activities described in paragraph 12 and shown in **Exhibit A** were all conducted in my laboratory at Lexicon Genetics Inc. in The Woodlands, Texas, in the United States of America.

12. **Exhibit A**, is a copy of a page from a laboratory notebook in which is affixed a copy of a "hHTG/PFAM LexGene Mining Form"dated prior to May 24, 2000. This form evidences that I had conceived and was in possession of the nucleic acid sequence that is presented in the above-captioned patent application as SEQ ID NO:1. This sequence is listed under the heading "hHTG Fragment Sequence:" and is that portion of a larger sequence known as AC040910 which I believe to be the relevant coding sequence. This relevant coding sequence and SEQ ID NO:1 in the above-captioned patent application are identical.

13. Based upon the foregoing evidence, I declare that the invention claimed in the above-captioned patent application was made in the United States prior to May 24, 2000.

14. We hereby declare that all statements made herein of our knowledge are true and that all statements made on information and belief are believed to be true; and further that these statements were made with the knowledge that willful false statements and the like so made are punishable by fine or imprisonment, or both, under Section 1001 of Title 18 of the United States Code and that such willful false statements may jeopardize the validity of the application or any patent issued thereon.

12/19/03
Date

D. Wade Walke

12/19/03
Date

John Scoville

Project initiated Wade Walke

SEC-99 Assigned Wade

hHTG/PFAM LexGene Mining Form

Meeting Date: **Wade Walke**

hHTG accession #: AC040910 **Date of Analysis:**
Proposed LexGene Class: SEC **Suggested by:** Wade Walke **PFAM family:** Thymosin

hHTG Fragment Sequence: >AC040910 (43787 43918) date: \SE0
atggcacacaaactagacctggaagaaattgccagcttggataaggccaagctgaaggccacagagatgcagaagaacactctgatgaccaaagagacc
acagagcaggagaagtggagtgaaatttcctga

PFAM hit alignment: >AC040910 ACCESSION:AC040910 NID:0 Homo sapiens Homo sapie
ns chromosome 9 clone RP11-211N10 map 9, LOW-PASS SEQUENCE S
AMPLING. /len=56294 HTGS_PHASE0 Length = 56294 Score = 50 (n/a bits), Expect = 7.8e-14, P =
7.8e-14 Identities = 29/41 (71%), Positives = 32/41 (78%)

```
Query:     1 SDKPDLEEIASFDKAKLKKTETQEKNPLPTKETIEQEKQAE 41
           + K DLEEIAS DKAKLK TE Q KN+L TKET EQEK +E
Sbjct: 43790 AHKLDLEEIASLDKAKLKATEMQ-KNTLMTKETTEQEKWSE 43907
```

Evaluate IP: gb|S54005|S54005 thymosin beta-10 [human, metastatic melanoma cell line, mRNA, 453 nt].
Length = 453 Score = 93.7 bits (47), Expect = 4e-17 Identities = 112/133 (84%), Positives = 112/133
(84%), Gaps = 3/133 (2%)

```
Query: 1   atggcacacaaactagacctggaagaaattgccagcttggataaggccaagctgaaggcc 60
           |||||| |||||| |||| ||| ||||| |||||||| ||||||||||||||||||||
Sbjct: 66  atggcagacaaaccagacatgggggaaatcgccagcttcgataaggccaagctgaagaaa 125

Query: 61  acagagatgcag---aagaacactctgatgaccaaagagaccacagagcaggagaagtgg 117
           || |||| ||||   |||||||| ||| |||||||||||||  |||||||||||| ||
Sbjct: 126 acggagacgcaggagaagaacaccctgccgaccaaagagaccattgagcaggagaagcgg 185

Query: 118 agtgaaatttcct 130
           |||||||||||||
Sbjct: 186 agtgaaatttcct 198
```

Evaluate homology significance: gp|HUMTHYMB10_1
Length = 49 Score = 56.6 bits (134), Expect = 5e-08
Identities = 33/44 (75%), Positives = 34/44 (77%), Gaps = 1/44 (2%)

```
Query: 1  MAHKLDLEEIASLDKAKLKATEMQ-KNTLMTKETTEQEKWSEIS 43
          MA K D+ EIAS DKAKLK TE Q KNTL TKET EQEK SEIS
Sbjct: 6  MADKPDMGEIASFDKAKLKKTETQEKNTLPTKETIEQEKRSEIS 49
```

Comment on likely biology: This may be poor sequence (phase 0) and is really just the known thymosin beta 10. This sequence will need to be confirmed. The entire exon is contained within the genomic sequence. thymosin beta 10 appears to be expressed in a wide range of tissues. It has been associated with many different functions including development of the nervous system to cancer. Its true function is still largely unknown.

Comment on pharmaceutical relevance and drugability: A potential therapeutic.

Corresponding OSTs: OST98997 (this may be the true thymosin beta 10)

ssed & Understood by me,	Date	Invented by	Date
BN		..ecorded by W.D. Walke	